4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA- 2021-M-0228, FDA- 2021-M-0202, FDA- 2021-M-0203, FDA- 2021-M-0178, FDA- 2021-M-0153, FDA- 2021-M-0135, FDA- 2021-M-0325, FDA- 2021-M-0303, FDA- 2021-M-0288, FDA- 2021-M-0421, FDA- 2021-M-0416, FDA- 2021-M-0355, FDA-2021-M-0354, FDA- 2021-M-0520, FDA- 2021-M-0615, FDA- 2021-M-0531, FDA- 2021-M-0527, FDA- 2021-M-0820, FDA- 2021-M-0769, FDA- 2021-M-0766, FDA- 2021-M-0676, FDA- 2021-M-0690, FDA- 2021-M-0656, FDA- 2021-M-0494, FDA- 2021-M-0915, FDA-2021-M-0911, FDA- 2021-M-0853, FDA- 2021-M-0805, FDA-2021-M-1046, FDA- 2021-M-1010, FDA- 2021-M-0991, FDA- 2021-M-0989, FDA- 2021-M-0975, FDA- 2021-M-0962, FDA-2021-M-1176, FDA-2021-M-1119, FDA-2021-M-1116, FDA-2021-M-0532, FDA- 2021-M-1058, FDA- 2021-M-1182, FDA-2021-M-1023, FDA-2021-M-1207, FDA-2021-M-1284, FDA-2021-M-1271, FDA-2021-M-1317, FDA-2021-M-1321, FDA-2021-M-1316, FDA-2021-M-1325, FDA-2021-M-1352, FDA-2022-M-0029, FDA-2022-M-0071, FDA-2022-M-0087, FDA-2022-M-0089, FDA-2022-M-0090, and FDA-2022-M-0171].

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing a list of premarket approval applications (PMAs) that have been approved from January 1, 2021, through February 14, 2022. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the internet and the Agency's Dockets Management Staff. This is the last notice of this kind considering FDA's rule discontinuing the practice of publishing such summaries in the *Federal Register*. As indicated in that rule, FDA

will continue to publish to make available on the internet and place on public display summaries of safety and effectiveness for approved PMAs.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket Nos. FDA- 2021-M-0228, FDA- 2021-M-0202, FDA- 2021-M-0203, FDA- 2021-M-0178, FDA- 2021-M-0153, FDA- 2021-M-0135, FDA- 2021-M-0325, FDA- 2021-M-0303, FDA- 2021-M-0288, FDA-2021-M-0421, FDA- 2021-M-0416, FDA- 2021-M-0355, FDA- 2021-M-0354, FDA- 2021-M-0520, FDA- 2021-M-0615, FDA- 2021-M-0531, FDA- 2021-M-0527, FDA- 2021-M-0820, FDA- 2021-M-0769, FDA- 2021-M-0766, FDA- 2021-M-0676, FDA- 2021-M-0690, FDA-2021-M-0656, FDA- 2021-M-0494, FDA- 2021-M-0915, FDA- 2021-M-0911, FDA- 2021-M-0853, FDA- 2021-M-0805, FDA-2021-M-1046, FDA- 2021-M-1010, FDA- 2021-M-0991, FDA- 2021-M-0989, FDA- 2021-M-0975, FDA- 2021-M-0962, FDA-2021-M-1176, FDA-2021-M-1119, FDA-2021-M-1116, FDA-2021-M-0532, FDA- 2021-M-1058, FDA- 2021-M-1182, and FDA-2021-M-1023, FDA-2021-M-1207, FDA-2021-M-1284, FDA-2021-M-1271, FDA-2021-M-1317, FDA-2021-M-1321, FDA-2021-M-1316, FDA-2021-M-1325, FDA-2021-M-1352, FDA-2022-M-0029, FDA-2022-M-0071, FDA-2022-M-0087, FDA-2022-M-0089, FDA-2022-M-0090, and FDA-2022-M-0171 for "Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing

and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Dharmesh Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2434, Silver Spring, MD 20993-0002, 301-796-3289, Dharmesh.Patel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is published in the *Federal Register*. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of

a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

Prior to February 14, 2022, the regulations provided that FDA publish a list of available safety and effectiveness summaries of PMA approvals and denials that were announced in the *Federal Register*. FDA issued a rule discontinuing this practice on January 13, 2022 (87 FR 2042). At that time, FDA committed to continue to publish lists of safety and effectiveness summaries of PMA approvals and denials on its website. The following list of approved PMAs for which summaries of safety and effectiveness that were placed on the internet from January 1, 2021, through February 14, 2022, will, therefore, be our last such list to be published in this manner. There were no denial actions during this period. The list in table 1 provides the manufacturer's name, the product's generic name or trade name, and the approval date.

Table 1.--List of Safety and Effectiveness Summaries for Approved PMAs and Safety and Probable Benefit Summaries for Approved HDEs Made Available from January 1, 2021, through February 14, 2022

PMA No., Docket No.	Applicant	Trade Name	Approval Date
P200003, FDA-2021-M-0070	Seno Medical Instruments, Inc.	Imagio® Breast Imaging System	1/11/21
P200028, FDA- 2021-M-0135,	Medtronic, Inc.	DiamondTemp™ Ablation System consisting of DiamondTemp™ AblaDiamondTemp Ablation Catheter (Models CEDT100S, CEDT200L, CEDTB300S, CEDTB400L); DiamondTemp™ RF Generator (Model CEDTG200); DiamondTemp™ Irrigation Pump (Model CEDTP100); DiamondTemp™ Irrigation Tubing Set (Model CEDTTS100); DiamondTemp™ Catheter-to-RF Generator Cable (Model CEDTC100); DiamondTemp™ GenConnect Cable (Model CEDTGC100); DiamondTemp™ EGM Cable (Model CEDTEGM100)	1/28/2021
P140029/S027, FDA- 2021-M-0153,	Q-Med AB	Restylane® Defyne	1/29/2021
P190005, FDA- 2021-M-0178,	Roche Diagnostics	Elecsys Anti-HBe, PreciControl Anti-HBe	2/3/2021

P200039, FDA- 2021-M-0202,	Shockwave Medical, Inc.	Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C^2 Coronary Intravascular Lithotripsy (IVL) Catheter	2/12/2021
P190013, FDA- 2021-M-0288	AED Battery Exchange, LLC.	AED Battery Exchange (Models 9146-ABE, G5-ABE, 5070-ABE, FR3-ABE)	2/13/2021
H200001, FDA- 2021-M-0203	Additive Orthopaedics, LLC.	Patient Specific Talus Spacer	2/17/2021
P190034, FDA- 2021-M-0228,	Roche Diagnostics	Elecsys Anti-HBs II, PreciControl Anti-HBs, Anti-HBs CalCheck	2/23/2021
P200029, FDA- 2021-M-0303	Boston Scientific Corporation	TheraSphere™	3/17/2021
P200025, FDA- 2021-M-0325	Bausch Health	ClearVisc Ophthalmic Viscosurgical Device (OVD)	3/23/2021
P200046, FDA- 2021-M-0354	Medtronic, Inc.	Medtronic Harmony Transcatheter Pulmonary Valve (TPV) System	3/26/2021
P200022/S003, FDA- 2021-M-0355,	Simplify Medical, Inc.	Simplify® Cervical Artificial Disc	4/1/2021
P200019, FDA- 2021-M-0416	Ventana Medical Systems, Inc.	VENTANA MMR RxDx Panel	4/22/2021
P980040/S124, FDA- 2021-M-0421	Johnson & Johnson Surgical Vision, Inc	TECNIS Synergy™ IOL, Model ZFR00V, TECNIS Synergy™ Toric II IOL, Models ZFW150, ZFW225, ZFW300, ZFW375, TECNIS Synergy™ IOL with TECNIS Simplicity™ Delivery System, Model DFR00V, TECNIS Synergy™ Toric II IOL with TECNIS Simplicity™ Delivery System, Model DFW150, DFW225, DFW300, DFW375	4/28/2021
P200002, FDA-2021-M-0418	AtriCure, Inc.	EPi-Sense® Guided Coagulation System	4/28/21
P140031/S125, FDA-2021-M-0473	Edwards Lifesciences, LLC.	Edwards SAPIEN 3 andSAPIEN 3 Ultra Transcatheter Heart Valve System	5/13/21
P200010/S001, FDA- 2021-M-0520	Guardant Health, Inc.	Guardant360 CDx	5/21/2021
P110027/S012, FDA- 2021-M-0531	QIAGEN GmbH	therascreen® KRAS RGQ PCR Kit	5/28/2021
P110033/S053 FDA- 2021-M-0527	Allergan	JUVÉDERM® VOLBELLA® XC	5/28/2021
P200010/S002, FDA- 2021-M-0494	Guardant Health, Inc.	Guardant360 CDx	5/28/2021

P100010/S110, FDA- 2021-M-0690	Medtronic, Inc.	Arctic Front AdvanceTM Cardiac Cryoablation Catheters, Arctic Front Advance ProTM Cardiac Cryoablation Catheters, FreezorTM MAX Cardiac Cryoablation Catheter, CryoConsole Manual Retraction Kit	6/18/2021
P200021, FDA- 2021-M-0615	Oticon Medical	Neuro Cochlear Implant System	6/23/2021
P110019/S115, FDA- 2021-M-0656	Abbott Vascular	XIENCE Alpine Everolimus Eluting Coronary Stent Systems (XIENCE Alpine EECSS), XIENCE Sierra Everolimus Eluting Coronary Stent Systems (XIENCE Sierra EECSS), and the XIENCE Skypoint Everolimus Eluting Coronary Stent Systems (XIENCE Skypoint EECSS)	6/25/2021
P140029/S032, FDA- 2021-M-0676	Q-Med AB, a Galderma affiliate	Restylane® Contour	6/28/2021
P200017, FDA- 2021-M-0766	Siemens Healthcare Diagnostics Inc	ADVIA Centaur® Anti-HBe2 (aHBe2) assay	7/14/2021
P190032/S001, FDA-2021-M-0707	Foundation Medical, Inc.	FoundationOne® Liquid CDx (F1 Liquid)	7/15/21
P130022/S039, FDA- 2021-M-0769	Nervo Corporation	Senza® Spinal Cord Stimulation (SCS) System	7/16/2021
P200037, FDA- 2021-M-0820	Kestra Medical Technologies, Inc.	ASSURE® Wearable Cardioverter Defibrillator (WCD) System (ASSURE System)	7/27/2021
P200011, FDA- 2021-M-0853	Pillar Biosciences, Inc.	ONCO/Reveal™ Dx Lung & Colon Cancer Assay	7/30/2021
P200045, FDA- 2021-M-0805	Bolton Medical, Inc.	RelayPro Thoracic Stent-Graft System	8/5/2021
P200049, FDA- 2021-M-0911,	Abbott Medical	Amplatzer™ Amulet™ Left Atrial Appendage Occluder	8/14/2021
P210001, FDA- 2021-M-0915	Ventana Medical Systems, Inc.	VENTANA MMR RxDx Panel	8/17/2021
P160045/S028, FDA- 2021-M-0962	Life Technologies Corporation	Oncomine® Dx Target Test	8/25/2021
P210007, FDA- 2021-M-0991	MicroTransponder Inc.	MicroTransponder® Vivistim® Paired VNS™ System (Vivistim® System)	8/27/2021
P050052/S129, FDA- 2021-M-0975	Merz North America, Inc.	RADIESSE® (+) Lidocaine injectable implant	9/1/2021
P180051, FDA- 2021-M-0989	TransMedics, Inc.	Organ Care System (OCS™) Heart System	9/3/2021
P160045/S029, FDA-2021-M-1023	Life Technologies Corporation	Oncomine™ Dx Target Test	9/15/2021
P190023, FDA- 2021-M-1010	Abbott Medical	Portico™ Transcatheter Aortic Valve Implantation System: Portico™ Transcatheter Aortic Heart Valve, FlexNav™ Delivery System, FlexNav™ Loading System	9/17/2021

P200004, FDA-2021-M-1046	ConMed Corporation	ConMed PadPro Multifunction Electrodes, ConMed PadPro Multifunction Electrode Adapters	9/26/2021
P200031, FDA- 2021-M-1058	TransMedics, Inc.	Organ Care System (OCS™) Liver	9/28/2021
P210026, FDA-2021-M-1116	Agilent Technologies, Inc.	Ki-67 IHC MIB-1 pharmDx (Dako Omnis)	10/12/2021
P190012, FDA-2021-M-1119	Spatz FGIA Inc.	Spatz3 Adjustable Balloon System	10/15/2021
P160046/S010, FDA-2021-M-0532	Ventana Medical Systems, Inc.	VENTANA PD-L1 (SP263) Assay	10/15/2021
P150031/S040, FDA-2021-M-1176	Boston Scientific Corporation	Vercise PC, Vercise Gevia and Vercise Genus DBS Systems	10/20/2021
P150038/S014, FDA- 2021-M-1182	INSIGHTEC, Inc	Exablate Model 4000 Type 1.0 and 1.1 System ("Exablate Neuro")	10/29/21
P130026/S070, FDA-2021-M-1207	Abbott Medical	TactiCath Contact Force Ablation Catheter, Sensor Enabled (Uni-Directional); TactiCath Contact Force Ablation Catheter, Sensor Enabled (Bi-Directional); TactiSys Quartz Equipment; Ampere RF Generator and Cool Point Irrigation Pump	11/4/21
P210020, FDA-2021-M-1284	Urotronic, Inc.	Optilume® Urethral Drug Coated Balloon	12/3/21
P190022, FDA-2021-M-1271	OPKO Health, Inc.	4Kscore® Test	12/7/21
P200035, FDA-2021-M-1317	OrganOx Limited	OrganOx metra® System	12/9/21
P210014, FDA-2021-M-1321	Svelte Medical Systems, Inc.	SLENDER Sirolimus-Eluting Coronary Stent Integrated Delivery System and DIRECT Sirolimus-Eluting Coronary Stent Rapid Exchange Delivery System	12/13/21
P200041, FDA-2021-M-1316	OrbusNeich Medical (Shenzhen) Co., Ltd.	Scoreflex NC Scoring PTCA Catheter	12/21/21
P200015/S011, FDA-2021-M-1325	Edwards Lifesciences LLC.	Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent	12/16/21
P200040, FDA-2021-M-1352	Delphinus Medical Technologies, Inc.	SoftVue Automated Whole Breast Ultrasound System with Sequr Breast Interface Assembly	10/6/21
P170002/S012, FDA-2022-M-0029	TEOXANE S.A.	RHA® Redensity™	12/22/21
P970051/S205, FDA-2022-M-0071	Cochlear Americas	Nucleus 24 Cochlear Implant System	1/10/22
P130022/S042, FDA-2022-M-0087	Nevro Corporation	Senza® Spinal Cord Stimulation (SCS) System	1/18/22

P840001/S469, FDA-2022-M-089	Medtronic Neuromodulation	Restore, Itrel, Synergy, Intellis, and Vanta Spinal Cord Stimulation Systems, Pisces, Specify and Vectris Spinal Cord Stimulation Leads	1/21/22
P080012/S068, FDA-2022-M-0090	Flowonix Medical, Inc.	Prometra® Programmable Infusion Pump System	1/12/22
P160048/S016, FDA-2022-M-0171	Senseonics, Incorporated	Eversense® E3 Continuous Glucose Monitoring System	2/10/22

II. Electronic Access

Persons with access to the internet may obtain the documents at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.

Dated: June 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-12371 Filed: 6/7/2022 8:45 am; Publication Date: 6/8/2022]